REMARKS

Reconsideration and allowance in view of the following remarks are respectfully requested.

Claims 1, 4, 5, 7 and 23-25 were rejected under 35 USC 103(a) as being unpatentable over Stadler in view of Natarajan. Applicant respectfully traverses this rejection.

Stadler relates to recording and analysing electrograms (EGM) for detection of ischemia using directional electrodes arranged with orthogonal sensing axis. Accelerometer sensors are disclosed as examples by the incorporation by reference of Mouchawar and Moberg.

In the second-last paragraph on page 4 of the Office Action, the Examiner acknowledges that Stadler does not disclose determining a frequency distribution of the recorded acceleration signal. Applicant notes that, as a consequence, Stadler also fails to disclose comparing such determined frequency distribution with a reference frequency distribution recorded previously.

In the last section on page 4 of the Office Action, the Examiner suggests that it would have been obvious for one having ordinary skill in the art to apply the teachings of Natarajan related to carrying out time-frequency analysis of electrogram signals to the Stadler system.

Applicant respectfully disagrees as to the obviousness of such a combination, and as to the form of the rejection in general.

To maintain a rejection, the Examiner has the burden of providing evidence of prima facie obviousness, see e.g. MPEP 2143 and In re Vaeck, 947 F.2d 488, 20 USPQ2d

1438 (Fed. Cir. 1991). To establish a prima facie case of obviousness it is preferable that the rejection show the following:

1. a suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings;

2. a reasonable expectation of success; and

3. the prior art reference (or references when combined) must teach or suggest all the claim limitations.

The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure.

In the Office Action, the Examiner fails to meet the above criteria 1, 2 and 3 for establishing a prima facie case of obviousness.

The following outlines the disclosures of Natarajan in relation to time-frequency analysis of electrogram signals and sensing of mechanical parameters.

Natarajan relates to recognising myocardial ischemia and/or infarction (MI/I), and describes the recording and analysis of electrograms and the sensing of other hemodynamical and mechanical parameters. More specifically, Natarajan discloses time-frequency analysis of electrograms (column 3, lines 32-39 and column 11, line 49 – column 12, line 8). An electrogram (EGM) consists of electrical signals recorded by electrodes at various locations in the heart as a function of time).

Elsewhere (column 3, lines 39-43), it is mentioned that hemodynamical and mechanical parameters (such as blood pressure, blood flow, etc.) can be sensed separately or in conjunction to the sensing of the EGM signals. At one instance (column 10, line

22), is it mentioned that a mechanical sensor element can be an accelerometer). The Applicant stresses the following observations:

- It is not mentioned that the accelerometer is used to record acceleration of parts of the heart, only that such an accelerometer may be used as a mechanical sensor, which is considered to be well known by one having ordinary skill in the art. Sensed mechanical parameters are suggested to be "blood pressure, blood flow, etc." (column 3, lines 41-42). Further, possible sensor locations are disclosed as "in the heart, on or in the vicinity of the heart, under the skin, under the musculature, implanted in the thoracic or abdominal cavity" (column 3, lines 22-27). Hence, several locations are given that differ from the location specified in the present claims, namely on, or immediately below, the outer surface of the heart.

- No sensed mechanical signals are shown, described or referred to in Natarajan, and there is no mention of time-frequency analysis of signals other than EGM signal at any point.

- A time-frequency distribution 719 is shown in Figure 7(a). This is a graph showing frequency as a function of time.

- It is nowhere mentioned that the data analysis applied to the EGM signals can also be applied to sensed mechanical parameters. At all instances where signal analysis is mentioned, this is specifically related to the EGM signals only.

1. <u>No suggestion or motivation to modify or combine</u>

There is no suggestion or motivation, either in Stadler, Natarajan, or in the knowledge generally available to one of ordinary skill in the art, to modify the Stadler

system related to signals from piezoelectric motion sensors placed on the heart to apply a time-frequency analysis which is only described in relation to electrogram signals.

There is no mention in either Stadler or Natarajan that suggests or motivates that the time-frequency analysis applied to the EGM signals can also be applied to sensed mechanical parameters.

2. No reasonable expectation of success

The output from a 3D piezoelectric motion sensor is three signals, each similar to those shown in the top graphs of Figures 1 and 2 of Moberg. The amplitude indicates the direction (along one dimension) and magnitude of the acceleration of the sensor. These signals do not directly indicate either speed or position of the sensor.

It is not disclosed in Natarajan how the time-frequency analysis could be applied to the accelerometer signals from the Stadler system. Neither Stadler nor Natarajan give any indication of how the time-frequency analysis from Natarajan should be applied to accelerometer signals? Which parameters should be extracted from a resulting time-frequency distribution? How such results should be interpreted, e.g. in relation to myocardial ischemia? While electrogram signals recorded at different positions of the heart are similar (main difference is the delay), the different segments of the heart moves very differently. Hence, while an EGM signal is a global parameter, the motion of a selected position on the outer surface of a heart is a regional parameter, which varies considerably with the selected position. Hence, the interpretation of a time-frequency distribution of the global EGM signals of Natarajan cannot be applied when interpreting analysis of regional acceleration signals recorded at different positions on the surface of the heart. Thus, even in the hypothetical case where the combination were carried out, it can not be expected that the time-frequency analysis of the EGM signals in Natarajan would yield applicable results if applied on signals from motion sensors placed on the heart.

3. Not all claim limitations are taught

Neither Stadler nor Natarajan discloses the claim limitation:

a. Determining a frequency distribution of a recorded acceleration signal. In this regard, the Examiner says that a time-frequency distribution is determined in Natarajan, but the claim explicitly specifies that, according to the invention, the frequency distribution must be of a recorded acceleration signal and that the distribution must be a frequency distribution (not a time-frequency distribution).

Frequency distributions and time-frequency distributions provide very different information, and the difference between them is explained in the following. A time-frequency distribution of a time dependent signal, as taught by Natarajan, gives the frequency content of a signal as it changes over time, and is typically calculated using a continuous transformation such as short-time Fourier transform (STFT). Thus, the time-frequency distribution tells, as graph 719 in Figure 7(a) of Natarajan, which frequencies are present in the signal, but not to which extent.

A frequency distribution of a time dependent signal gives the relative strengths of the different frequencies present in the signal, and is typically calculated using a discrete Fourier transform such as fast Fouruer transform (FFT). Thus, the frequency distribution gives, as graphs in Figures 4a-c of the present invention, the relative strengths of different frequencies present in the signal. As an example, Figures 4b and 4c of the present invention shows frequency distributions from before and after LAD occlusion, see also section [0059]. The same frequencies are present in both graphs, but their relative strength differs to a large degree, and this can be used determine occlusion occurring prior to fibrillation (in this example, the complete LAD occlusion leads to almost immediate fibrillation which is easily detectable, in a clinical setting, a partly occlusion which would not lead to immediate fibrillation could be detected). The time-frequency

distributions of graphs in Figures 4b and 4c would most likely not be distinguishable, as the same frequencies are present before and after LAD occlusion.

Thus, the difference between frequency distributions and time-frequency distributions is substantial, and the claim limitation "determining a frequency distribution of a recorded acceleration signal" is not taught by Stadler or Natarajan.

For all the reasons advanced above, reconsideration and withdrawal of the Examiner's rejection based on Stadler and Natarajan is requested.

Claims 2 and 3 were rejected under 35 USC 103(a) as being unpatentable over Stadler and Natarajan in view of Matsumoto. Applicant respectfully traverses this rejection.

Claims 2 and 3 are submitted to be patentable over Stadler and Natarajan for the reasons advanced above. The Examiner's further reliance on Matsumoto does not overcome the deficiencies of the primary combination noted above. Reconsideration and withdrawal of the rejection are requested.

Claim 6 was rejected under 35 USC 103(a) as being unpatentable over Stadler and Natarajan in view of Dickinson. Applicant respectfully traverses this rejection.

Claim 6 is submitted to be patentable over Stadler and Natarajan for the reasons advanced above. The Examiner's further reliance on Dickinson does not overcome the deficiencies of the primary combination noted above. Reconsideration and withdrawal of the rejection are requested.

Claim 8 was rejected under 35 USC 103(a) as being unpatentable over Stadler and Natarajan in view of Hess. Applicant respectfully traverses this rejection.

Claim 8 is submitted to be patentable over Stadler and Natarajan for the reasons advanced above. The Examiner's further reliance on Hess does not overcome the

deficiencies of the primary combination noted above. Reconsideration and withdrawal of the rejection are requested.

All objections and rejections having been addressed, it is respectfully submitted that the present application is in condition for allowance and an early Notice to that effect is earnestly solicited.

All claims are in good condition for allowance. If any small matter remains outstanding, the Examiner is requested to telephone applicants' attorney. Prompt reconsideration and allowance of this application is requested.

The Commissioner is hereby authorized to charge any deficiency, or credit any overpayment, in the fee(s) filed, or asserted to be filed, or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Account No. 14-1140.

Respectfully submitted,

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